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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,801	10/16/2003	Shibnath Ghosal	4822-129 US	7933
26817 7590 06/15/2007 MATHEWS, SHEPHERD, MCKAY, & BRUNEAU, P.A. 29 THANET ROAD, SUITE 201 PRINCETON, NJ 08540			EXAMINER HUYNH, CARLIC K	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 06/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/686,801	Applicant(s) GHOSAL, SHIBNATH	
	Examiner Carlic K. Huynh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-11,13-22 and 24-37 is/are pending in the application.
- 4a) Of the above claim(s) 28,29 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-11,13-22 and 24-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of applicants' amendments and remarks filed on March 27, 2007 is acknowledged.

Status of the Claims

1. Claims 1-2, 5-11, 13-22, and 24-37 are pending in the application, with claims 3-4, 12, and 23 having been cancelled, in response to the non-final rejection submitted on February 20, 2007, and claims 28-29 and 35 having been withdrawn from consideration, in response to the non-final rejection submitted on February 20, 2007. Accordingly, claims 1-2, 5-11, 13-22, and 34-37 are being examined on the merits herein.
2. Claims 1-2, 5-11, 13-22, and 24-37 are drawn to a composition and thus intended use is not given any patentable weight.

Response to Arguments

3. Applicant's arguments with respect to claims 1-27 and 30-35 in an amendment filed on March 27, 2007 have been considered but are moot in view of the new ground(s) of rejection.

The arguments are moot because:

- a. The 35 USC § 112, first paragraph rejections to claims 1-27 and 30-35 have been withdrawn in light of the amendments;
- b. The 35 USC § 112, second paragraph rejection to claims 1, 12, 14, and 34-35 have been withdrawn in light of the amendments;

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c. The 35 USC § 102 rejection to claims 1, 5, 9-11, 22, 24-25, and 27 have been withdrawn because the arguments were found persuasive;

d. The 35 USC § 103 rejection to claims 2-4, 6-8, 12-21, 23, 26, and 30-35 have been withdrawn because the arguments were found persuasive in part.

The reference Huang et al. (US 2003/0152588) qualifies as prior art under 35 USC § 102(a) which states:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Huang et al. was published on August 14, 2003 whereas the filing date of the instant application is October 16, 2003. Thus Huang et al. qualifies as prior art under USC § 102(a).

The reference Huang et al. (US 2003/0152588) also qualifies as prior art under 35 USC § 102(e) which states:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Huang et al. was published on August 14, 2003 with a filing date of January 14, 2002 whereas the filing date of the instant application is October 16, 2003. Thus Huang et al. qualifies as prior art under USC § 102(e).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2, 5-11, 13-22, 24-27, 30-34, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosal (US 6,362,167) in view of Ghosal (US 6,440,436), as evidenced by Pushpangadan et al. (US 2003/0185913), and in further view of Boynton et al. (US 5,087,623).

Ghosal (US 6,362,167) teaches extracts of the fruit of the *Embllica officinalis* plant and its administration to provide antioxidant activity to block free radical processes without pro-oxidant side reactions, optionally including an additional antioxidant (column 3, lines 59-63).

Ghosal (US 6,362,167) does not teach phenolic anti-oxidants from purified shilajit.

Ghosal (US 6,440,436) teaches a purified shilajit composition comprising oxygenated dibenzo- α -pyrone (DBP), its di- and/or tetramers, and their esters as well as carrier molecules which are low-to-medium molecular weight fulvic acids (column 2, lines 62-66; and column 3, lines 57-59). The molecular weight of the fulvic acids ranges from 700 to 2000 (column 5, lines 52-53). Pharmaceutical formulations of the purified shilajit composition are also taught (abstract).

As evidenced by Pushpangadan et al., herbal health compositions can be used to control blood sugar levels in patients with diabetes (page 2, paragraph [0014]). Pushpangadan et al. also disclose commercial herbal anti-diabetic products containing Shilajit and *Phyllanthus emblica* (pages 9-10, Table 1).

Hyperglycemia is defined as abnormally high concentrations of glucose in the circulating blood especially in patients with diabetes.

Thus, the extract from the fruit of the *Emblica officinalis* plant and purified shilajit can be used to treat hyperglycemia in patients with diabetes.

Neither Ghosal (US 6,362,167) nor Ghosal (US 6,440,436) teach the phenolic anti-oxidant complex with chromium.

Boynton et al. teach a treatment for controlling high blood serum glucose levels comprising administering chromic picolinate (abstract). The chromium is known to improve glucose tolerance (column 2, lines 19-20).

Boynton et al. also teach trivalent chromium in the amount of 200 μ g of chromium or 12.5% chromium content (column 3, line 32 and column 7, lines 19-20). Additionally, the chromium tripicolinate is synthesized by combining picolinic acid and chromic chloride in deionized water, of which the final product (chromium tripicolinate) is air-dried (column 7, lines 3-13).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the extracts of Ghosal (US 6,362,167) and Ghosal (US 6,440,436) as evidenced by Pushpangadan et al. to contain chromium because the chromic picolinate of Boynton et al. can be used to control high blood serum glucose levels and according to Pushpangadan et al. and Boynton et al., both the extracts from *Phyllanthus emblica* fruit and purified shilajit and chromium are used to control high blood serum glucose levels.

The motivation to combine the extracts of Ghosal (US 6,362,167) and Ghosal (US 6,440,436) as evidenced by Pushpangadan et al. to the chromic picolinate compound of Boynton et al. is that the extracts from *Phyllanthus emblica* fruit and purified shilajit of Ghosal (US

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6,362,167) and Ghosal (US 6,440,436) and the chromic picolinate compounds of Boynton et al. control high blood serum glucose levels.

Regarding chromium content in the complex, as recited in claims 7 and 26, it is noted that Boynton et al. teach providing chromium picolinate will yield a composition containing 12.5% chromium content, which closely meets the amount of chromium content set forth in claims 7 and 26. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of chromium picolinate provided in a composition, according to the guidance set forth in Boynton et al., to provide a composition having desired chromium content. It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding chromium content in the complex, as recited in claims 9, 19, and 27, it is noted that Ghosal teaches providing fulvic acids in a composition with Mw 700-2000, which closely meets the amount of chromium content set forth in claims 9, 19, and 27. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the Mw of fulvic acids provided in a composition, according to the guidance set forth in Ghosal, to provide a composition having desired Mw of fulvic acids. It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

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Regarding *Phyllanthus emblica* as recited in the instant claim 13, it is disclosed in the instant specification that *Emblica officinalis* is synonymous with *Phyllanthus emblica* (page 8, paragraph 3).

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 5, 9-11, 13-16, 18, 20, 31, 33, and 36-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 8 of Ghosal (US 6,440,436).

Claim 8 of Ghosal (US 6,440,436) is directed to the purified shilajit composition which consists essentially of oxygenated dibenzo- α -pyrones in metal ion conjugate forms. Conjugates are known in the art to be joined or paired. A complex is known in the art as a combination of

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two or more compounds without covalent binding. As such, a complex can be view as a specific type of conjugate.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 8 of Ghosal is the purified shilajit composition which consists essentially of oxygenated dibenzo- α -pyrones in metal ion conjugate forms, which is the same extract of the fruit of the *Emblica officinalis* plant and the purified shilajit composition used in a composition for the treatment of a condition comprising a phenolic antioxidant-chromium complex in the instant claims 1, 5, 9-11, 13-16, 18, 20, 31, 33, and 36-37. Thus the extract of the fruit of the *Emblica officinalis* plant and the purified shilajit composition are not patentably distinct between each of the Ghosal applications and the instant application.

6. Claims 1, 5, 9-11, 13-16, 18, 20, 31, 33, and 36-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 8 of Ghosal (US 6,440,436) and claim 1 of Ghosal (US 6,869,612).

The conflicting claims are not patentably distinct. Claim 8 of Ghosal (US 6,440,436) and claim 1 of Ghosal (US 6,869,612) are directed to the purified shilajit composition, which consists essentially of oxygenated dibenzo- α -pyrones in metal ion conjugate forms. Conjugates are known in the art to be joined or paired. A complex is known in the art as a combination of two or more compounds without covalent binding. As such, a complex can be view as a specific type of conjugate. The purified shilajit composition, which consists essentially of oxygenated dibenzo- α -pyrones in metal ion conjugate forms is the phenolic antioxidant-chromium complex of the instant claims.

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Thus the oxygenated dibenzo- α -pyrones in metal ion conjugate forms of Ghosal (US 6,440,436) and Ghosal (US 6,869,612) and the phenolic antioxidant-chromium complex of the instant application are not patentably distinct.

7. Claims 1, 5, 9-11, 13-16, 18, 20, 31, 33, and 36-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 46, 51, and 55 of copending Application Ghosal (US 2006/0062863).

The conflicting claims are not patentably distinct. Claims 18, 46, 51, and 55 of Ghosal (US 2006/0062863) are directed to a composition that is combined with the antioxidant is chromium complexed with *Phyllanthus emblica* extract. The phenolic antioxidant is the *Phyllanthus emblica* extract of the instant claims and the chromium is the chromium of the instant claims. Thus the phenolic antioxidant-chromium complex is not patentably distinct between Ghosal (US 2006/0062863) and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

Conclusion

8. No claims are allowed.

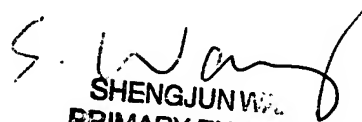
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh


SHENGJUN WANG
PRIMARY EXAMINER